

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 32-R-0003  
CUSTOMER NUMBER: 770

FORM APPROVED  
OMB NO. 0579-0036

**ANNUAL REPORT OF RESEARCH FACILITY**  
(TYPE OR PRINT)

Eli Lilly And Company  
Lilly Corporate Center  
Indianapolis, IN 46285

NOV 13 2005

Telephone: (317) -276-2000

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, or experimentation, or held for these purposes. Attach additional sheets if necessary)

FACILITY LOCATIONS ( Sites ) - See Attached Listing

**REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY ( Attach additional sheets if necessary or use APHIS Form 7023A )**

A.  Animals Covered By The Animal Welfare Regulations	B. Number of animal being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, res or interpretation of the teaching, research, experiments, surgery, or tests. ( An explanation of the procedures producing pain or distress in these animals and the reas such drugs were not used must be attached to this report	F.  TOTAL NUMBER OF ANIMALS  ( COLUMNS C + D + E )
1. Dogs	2	5	600	25	632
2. Cats		1	53		54
3. Guinea Pigs		232	450		682
4. Hamsters			1004		1004
5. Rabbits		537	225	9	771
6. Non-human Primates	3	1	419		423
7. Sheep					
8. Pigs					
9. Other Farm Animals					
10. Other Animals					
Gerbils		1786	160	856	2802

**ASSURANCE STATEMENTS**

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and an Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL  
( Chief Executive Officer or Legally Responsible Institutional Official )

(b)(6), (b)(7)(c)

DATE SIGNED

11/17/05

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**ATTACHMENT TO ANNUAL REPORT OF RESEARCH FACILITY**

For the period of October 1, 2004 through September 30, 2005

**Category "E" Experimentation****Eli Lilly and Company  
Indianapolis, IN 46285****Registration No. 32-R-0003**

Animals upon which experiments, research, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests.

Species	Number of Animals	Explanation
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<u>Dogs</u>	25	Toxicology
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These animals were used in the toxicological evaluation of drug candidates, novel pharmaceuticals. In some studies, the degree of toxicity was unexpectedly severe. When adverse clinical signs were detected, animals were provided veterinary and supportive care. Animals were euthanized when it was determined that pain or distress could not be alleviated. Administration of analgesics or tranquilizers would have confounded interpretation of the experimental results and the dogs were euthanized. Despite careful study design, supportive care, and adjustments to study protocols, animals in toxicology studies used in the evaluation of new drug candidates may experience unanticipated events. U.S. and O.U.S. regulations and guidelines for animal studies to support human clinical trials, specifically 21 CFR 312.23 (a)(8)(ii) and ICH SF4, require these studies.

<u>Gerbils</u>	856	Neuroscience
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These gerbils were used in studies of compounds that have shown positive results in *in vitro* screening tests. The animals were administered compounds and observed for overt behavioral changes involving neurological or motor deficits. Following the procedure, animals were immediately euthanized. Pharmaceutical intervention with sedatives, tranquilizers or analgesics would have invalidated the experimental objectives.

<u>Rabbits</u>	9	Toxicology
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These animals were used in the toxicological evaluation of drug candidates. In some studies, the degree of toxicity was unexpectedly severe. When adverse clinical signs were detected, animals were provided veterinary and supportive care. Animals were euthanized when it was determined that pain or distress could not be alleviated. Administration of analgesics or tranquilizers would have confounded interpretation of the experimental results, and the animal was euthanized. Despite careful study design, supportive care, and adjustments to study protocols, animals in toxicology studies used in the evaluation of new drug candidates may experience unanticipated events. U.S. and O.U.S. regulations and guidelines for animal studies to support human clinical trials, specifically 21 CFR 312.23 (a)(8)(ii) and ICH SF4, require these studies.

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**Exceptions to the Regulations and Standards**

**Eli Lilly and Company  
Indianapolis, IN 46285**

**Registration No. 32-R-0003**

1. Identify the IACUC approved exception to the standards

None

2. Describe the IACUC approved exception to the standards

None

3. Species of animal used

Not applicable

4. Number of animals used

Not applicable

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### **Sites and Locations and Listing**

**Eli Lilly and Company  
Indianapolis, IN 46285**

**Registration No. 32-R-0003**

This institution has been designated by the Agency as a single "site". The animal care and use facilities within this site designation are in multiple buildings in two locations.

- Eli Lilly and Company, Lilly Corporate Center, Indianapolis, Indiana 46285
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(b)(2)High, (b)(7)f

Any requests for information or access to the site should be made through the Corporate Center location.